Customer Safety Advisory Notice
CAN 003-2018

To: Director of the Radiology Department
Director of the Nuclear Medicine / PET Imaging Department
Risk Management Officer
Users of Siemens Healthineers' Biograph mCT and Biograph Horizon systems

Re: **Biograph mCT and Biograph Horizon system power connector issue**

Dear valued Siemens Healthineers customer,

This letter is to inform you that the screws to the system power connection terminal may be loose.

When does this malfunction occur and what are the potential risks?

This issue affects Biograph mCT and Biograph Horizon systems. If you are receiving this letter, the power connector on your device may have fasteners which are not adequately tightened.

This condition could cause the system power connection plug to overheat and lead to a potential fire. The system is designed in compliance with IEC 60601 and all materials are UL 94 V0 fire rated; therefore, there is no immediate risk to the patient and/or operators of your system. In the event overheating occurs, the system might cease functioning or you might notice a distinct burning odor. If either of these events occurs, please stop use of your system and contact your Siemens Healthineers service representative.

How can you help to avoid the potential risk of this issue?

At this time, there is no action you need to take.

What has been done by the manufacturer to address this issue?

Siemens Healthineers' service organization is addressing the issue through a service visit to check that your system power connector terminal screws are torqued to the proper specification.

Please ensure that this customer advisory notice is placed in the *Biograph Operator's Guide* and disseminated to all operators of Biograph mCT and mCT Flow. Please ensure that this customer advisory notice is placed in the *Biograph Horizon Operator's Manual for Examination and Acquisition* and disseminated to all operators of Biograph Horizon. If this equipment is no longer in your possession, we kindly ask that you forward this letter to the new owner of the equipment, and please inform Siemens Healthineers about the change in ownership.

Adverse events or quality problems experienced with the use of this product should be reported to Siemens Healthineers through the contact information provided below and may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

If you have any questions regarding this advisory notice, please contact your local Siemens Healthineers representative at the contact numbers provided below.

- America: 1-800-888-7436
- Europe, Middle East, and Africa: +49 9131 940 4000
- Asia and Australia: +86 (21) 3811 2121

Sincerely,

Matt Shah
Vice President, RA/QA & EHS
Molecular Imaging
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